UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: BeWanda Alexander

From: Clayton Myers, Entomologist **Date**: April 2, 2012 4-2-12

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode:	**381023**
Decision no.:	435344
Submission no:	876525
Action code:	R260
Product Name:	Sergeant's Bifenthrin Shampoo (with oatmeal) for Dogs
EPA Reg. No or File Symbol:	2517-RGO
Formulation Type:	Pet Shampoo

Ingredients statement from the label with PC codes included: Bifenthrin, 0.05%, PC: 128825
Application rate(s) of product and each active ingredient (lbs. or gallons/1000 sqnare feet or per acre as appropriate; and g/m^2 or mg/cm^2 as appropriate): Shampoo: "to lathering" according to label. Reapplication interval of 15 days (2 weeks). Studies evaluated the rate of 5 g product/kg on dogs, equivalent to specific ai rates ranging from 1.0 to 4.0 mg ai/kg.

I. Action Requested: Data was submitted to support pest claims for a new dog shampoo product

II. Background: The registrant seeks to register a new use, bifenthrin shampoo product for control of fleas and ticks and repellence of mosquitoes on dogs, with 2 week (15 day claims). The registrant has submitted 6 studies to support efficacy claims.

III. MRID Summaries: (Primary Reviews attached)

a. MRID 48122213

(1) Non-GLP submission
(2) This document summarizes the 5 actual study submissions made in support of this new product, and presents no new data
(3) Authors conclude that efficacy is supported for fleas and brown dog ticks to varying degrees. The primary author summarizes the findings on other studies regarding support of efficacy claims.
(4) The study is a descriptive overview and is supplemental to the application.

b. MRID 48122214

(1) Non-GLP
(2) A laboratory study was conducted with 12 dogs, to assess efficacy against *Ixodes* ticks exposed to clipped hair treated with the product. 6 dogs were treated, 6 were left as an untreated control. Three days after treatment, hair was cliped from the dogs, and *Ixodes scapularis* nypmhs were exposed to the hair for 48 hours. Percent efficacy was calculated using Abbott's formula.
(3) The test material provided 88% efficacy against nymphs at 24 hours and 100% at 48 hours.
(4) The study is adequate to support a kills claim against Black-legged ticks (*Ixodes*), and supports the claim for killing ticks that may transmit Lyme disease. The study does not support residual efficacy claims beyond 5 days after treatment.

c. MRID 48122215

(1) Non-GLP

(2) A laboratory study was conducted to evaluate flea and *R. sanguineus, A. americana, and Ixodes scapularis* tick efficacy and mosquitoe efficacy using 2 groups of 6 dogs. The treatement group dogs were treated with bifenthrin shampoo to an equivalent dosage of 2.50 mg ai/kg (5 g product/kg). Dogs were infested with fleas and *R. sanguineus* ticks on the day before treatment. Dogs were re-infested with new fleas and *A. americanum* ticks on day 7. Flea and tick counts were made on days 1, 2, and 3 after treatment and on days 8, 9, and 10 after treatment. 1, 2, 8, and 9 were timed hand counts, with days 3 and 10 done via complete removal. For *Ixodes*, hair was clipped on days 3 and 12 and assessed against nymphs in petri dishes. Nymph mortality was assessed at 24 and 48 hours. Mosquitoe efficacy was assessed using 'Gerber' type exposure cages, with exposure to 25 unfed mixed male and female mosquitoes. Mosquitoes landing on the dogs within the first five minutes of exposure were counted. Female mosquitoes were collected and squashed to determine the presence of a blood meal. *Culex quinquefasciatus* were used on days 6-7 and *Aedes aegypti* were used on days 7-13. Mortality/repellence was calculated using Abbott's formula.

(3) The test material was effective against the initial infestation of fleas and *R. sanguineus*. It was not effective against the 7 day reinfestation of fleas. It was effective against the *A. americanum* infestation within 48 hours of exposure. Clipped hair was effective against *Ixodes scapularis* at both 24 and 48 hours. The test material was not effective at preventing landings/killing of mosquitoes, but was effective at preventing blood feeding.

(4) This study is adequate to support killing claims against fleas and ticks, including ticks that may transmit Lyme disease. It does not support any residual control claims against fleas beyond those on the animal at the time of treatment. Claims are supported for repellence of mosquitoes and protection from blood feeding, but not for killing mosquitoes/prevention of landing on the animal.

d. MRID 48122216

(1) Non-GLP

(2) A laboratory study was conducted to evaluate flea and *R. sanguineus*, and *D. variabilis* tick efficacy, and mosquitoe efficacy using 4 groups of 6 dogs. 2 groups were treated and 2 were used as controls. Treated dogs were treated 0.05% bifenthrin shampoo at ai dosage of 2.50 mg/kg. One each of the treated groups were infested dosed with 50 American Dog ticks and 50 Brown dog ticks, respectively. Each was also infested with 100 cat fleas. Dogs were re-infested on days 7 and 14. Additionally, the dogs in one treated test group were re-infested with fleas at day 21. Flea and tick counts were made on days 1, 2, 8, 9, 15, 16, 22 and 23. Day 1, 8, 15, and 22 counts were timed hand counts while others were destructive removal counts. Mosquito tests were conducted on day 19. Dogs were anesthetized and confined for one hour in 'Gerber' exposure cages. Mosquitoes that landed during the first 5 minutes of exposure were counted. Female mosquitoes were collected for assessment of blood meals. Mortality/repellence was calculated using Abbott's formula.

(3) The test material was effective against fleas for 15 days, and *D. variabilis* for up to 9 days. It was ineffective against the initial infestation of *R. sanguineus* but was effective at 7 and 14 days. The test material was not effective at killing or preventing landing of mosquitoes, but was effective at preventing blood feeding.

(4) This study is adequate to support a 15 day control claim against fleas, and for up to 7 days on ticks (14 days for *R. sanguineus*). Claims are reported for repellence of mosquitoes, and protection from blood feeding, but not for killing or prevention of landing on the animal.

e. MRID 48122217

(1) Non-GLP

(2) A laboratory study was conducted to evaluate a number of bifenthrin shampoo formulations for control efficacy against cat fleas and *R. sanguineus* on dogs. Dogs were acclimated for 14

days and washed. Four formulations of bifenthrin shampoo were evaluated, including the 0.05% formulation proposed, equating to approximately 2.0 mg ai/kg animal (no rate is specified on the label, but approximately 4g/kg were applied to dogs). 3 dogs were placed per group in each of 4 treatment groups and an untreated control group. For treated dogs, shampoo was lathered and remained on each dog for 5 minutes, then rinsed off, with blow drying. Flea (100) and tick (50) infestations were made on the day of treatment, and re-infestations were made on days 6 and 13. Counts were made on days 1 and 2, and again on days 7 and 8, and on days 14 and 15. 24 hour counts were visual hand counts, while 48 hour counts were made via removal. For each evaluation, efficacy was calculated using Abbott's Formula.
(3) Test materials only provided acceptable efficacy against existing flea infestations, within 24 and 48 hours after treatment. Residual efficacy against flea reinfestations was not acceptable. For ticks, efficacy was adequate for the proposed 0.05% treatment (exceeding 94%) through day 15.
(4) The primary reviewer concurs with these conclusions. The study is adequate to support efficacy claims against *R. sanguineus* for 15 days after treatment.

e. **MRID 48122218**

(1) Non-GLP
(2) A laboratory study was conducted to evaluate a 0.025% bifenthrin shampoo formulation for control efficacy against cat fleas and *D. variabilis* and *R. sanguineus* ticks on dogs. Dogs were acclimated for 14 days and pre-qualified for tick retentions. Bifenthrin shampoo was applied equating to approximately 1.25 mg ai/kg animal (this is lower than the proposed label directions for the 0.05% product). 6 dogs were placed per group in 2 equivalent treatment groups and an untreated control group. For treated dogs, shampoo was lathered and remained on each dog for 5 minutes, then rinsed off, with blow drying. One treatment group was used to evaluate *Dermacentor* while the other was used for evaluation of *Rhipicephalus* while fleas were evaluated in both groups. Flea (100) and tick (50) infestations were made on the day of treatment, and re-infestations were made on day 7. Counts were made on days 1 and 2, and again on days 8 and 9. 24 hour counts were visual hand counts, while 48 hour counts were made via removal. For each evaluation, efficacy was calculated using Abbott's Formula.
(3) Test materials only provided acceptable efficacy against existing flea infestations, within 24 and 48 hours after treatment. Residual efficacy against flea reinfestations was not acceptable. For *D. variabilis*, efficacy never exceeded 67% by 48 hours after initial treatment. Subsequent residual efficacy against reinfestations were also unacceptable, at 28% for 48 hours after the 7 day reinfestation. For *R. sanguineus*, efficacy at 48 hours after initial treatment was 85% and only 50% for 48 hours after the 7 day reinfestation.
(4) The primary reviewer concurs with these conclusions. The study is inadequate to support any residual control claims against fleas and ticks, and only supports killing claims against fleas.

IV. RECOMMENDATIONS:

(1) Labeling:

(a) What pests and site/pest combinations may be added as follows to the label based on the submitted or cited data?

-Fleas: Kills claim, and residual efficacy for 7 days.
-Black-legged (Deer) Ticks: Kills claim, and residual efficacy for 5 days.
-Lone Star Ticks: Kills claim, no residual claims supported
-Brown Dog Ticks: Kills claim and residual control for 15 days (2 weeks).
-Ticks except Dermacentor: Kills claims are supported against Black Legged Ticks, Deer Ticks, and Lone Star Ticks, but because efficacy was not supported for American Dog ticks, the general tick claim killing claim must be qualified to exclude them
-Mosquitoes: Prevents blood feeding. General kill claim is not supported, but repellence is acceptable for one week (since *Culex* data was only evaluated through 6 days). Data for *Anopheles* was not submitted and must be

required conditionally

(b) What pests and site/pest combinations must be removed from the label?

General Tick claims (not supported because no American Dog Tick data were submitted or cited). All killing claims against ticks must either be species specific or qualified to exclude American Dog Ticks, unless additional data is submitted or cited.

(c) List changes to the directions for use:

An application rate must be added to the label, equivalent to the dosing of 2.5 mg ai/kg animal, expressed in some minimal rate statement: expression in teaspoons and/or fluid ounces of shampoo per 10 lbs of animal weight is preferred, rather than a weight measurement, which would be impractical for a user to measure.

(d) List changes to the optional marketing claims:

-All general claims of 15 day and/or 2 week efficacy must be revised to only include fleas. Tick efficacy is not supported for this duration.
-All repels and prevention of blood feeding claims for mosquitoes must have a duration no longer than 7 days (one week)
-All claims referring to ticks must be revised to exclude American Dog Ticks, including Kill claims.

The following marketing claims must be deleted from the label (line by line, pages 1-2):

~~"Kills Fleas & Ticks for 15 days/2 weeks"~~
~~"Kills for 15 days/2 weeks Fleas and Ticks"~~
~~"Kills Ticks for 15 days/2 weeks"~~ (Flea killing claim at this duration is acceptable)
~~"Repels and prevents blood feeding by mosquitoes for up to 2 weeks"~~ (only 1 week is acceptable)
~~"Repels mosquitoes for up to 15 days/2 weeks"~~ (only 1 week is acceptable)

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-13

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert W. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert W. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-13. Summary Analyses of Efficacy Data for Biphenthrin Shampoos Against Fleas, Ticks and Mosquitoes on Dogs. Sharp, M. 2010.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Research, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	23/02/2010
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since there was no quality assurance auditing.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825

CAS NO.: 82657-04-3
FORMULATION TYPE: Liquid shampoo
PRODUCT APPLICATION RATE(S): Not provided
ACTIVE INGREDIENT APPLICATION RATE(S): Not provided

PROPOSED LABEL MARKETING CLAIMS:

Kills Fleas [&] [Ticks] for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas [and] Ticks
Active against fleas
Active against ticks
Kills Fleas [for [15 days] [2 weeks]], Ticks [for [15 days] [2 weeks]]
Kills Fleas [and] Ticks for [15 days] [2 weeks]
Kills Ticks for [15 days] [2 weeks]
Kills adult Fleas [for up to [15 days] [2 weeks]]
Kills [fleas] [and] [ticks]
Repels and prevents blood feeding by mosquitoes for up to 2 weeks
Repels mosquitoes [for up to [15 days [2 weeks]]
Kills ticks that may carry Lyme Disease
Long lasting against ticks and mosquito feeding
Kills fleas and ticks on dogs

STUDY REVIEW

Purpose: This is a summary of five previously-conducted studies that determined the efficacy of bifenthrin against fleas, ticks, and mosquitoes on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test material was a shampoo containing bifenthrin (0.025 to 0.075% w/w), applied at a dose of 5.0 g/kg, to deliver bifenthrin dose rates of 1.0 to 4.0 mg/kg. The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Flea (scientific name not provided), sex not reported, adults; tick (*Rhipicephalus sanguineus*), sex not reported, adults; tick (*Amblyomma americanum*); sex not reported, adults; tick (*Dermacentor variabilis*); sex not reported, adults; tick (*Ixodes scapularis*), sex not reported, nymphs; mosquito (*Aedes aegypti*), males and females, adults; mosquito (*Culex quinquefasciatus*), males and females, adults.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: The study summarizes the results of five previous studies. In study 1 (MRID 481222-17), four groups of dogs (3 dogs/group) were infested with fleas and ticks. One day later, shampoo containing 0.025%, 0.050%, 0.075%, or 0.100% bifenthrin (providing doses of 1, 2, 3, and 4 mg/kg, respectively) was applied to three groups, and the fourth group served as an untreated control. The dogs were re-infested at 6 and 13 days, and the surviving fleas and ticks were counted over 15 days after treatment. All the treatments were effective against the initial infestation of fleas, but not against the re-infested fleas. The three highest dose rates were effective against all infestations of ticks; the lowest dose was effective against the initial infestation of ticks, and also effective 24 hours after the re-infestation on day 13.

In study 2 (MRID 481222-18), four groups of dogs (6 dogs/group) were infested with fleas and ticks. One day later, shampoo containing 0.025% bifenthrin (providing a dose of 1.25 mg/kg) was applied to two groups, and two groups served as untreated controls. The dogs were re-infested on day 7, and surviving fleas and ticks were counted over 9 days after treatment. The test material was effective against the original flea infestation for up to 48 hours, but not effective thereafter. The test material was ineffective against ticks infested at any time.

In study 3 (MRID 481222-16), four groups of dogs (6 dogs/group) were infested with fleas and ticks. One day later, shampoo containing 0.050% bifenthrin (providing a dose of 2.50 mg/kg) was applied to two groups, and two groups served as untreated controls. The dogs were re-infested with on days 7 and 14. Additionally, the dogs in one test material group and one control group were re-infested with fleas only on day 21. Surviving fleas and ticks were counted over 23 days after treatment. On day 19, dogs were exposed for one hour to *Culex quinquefasciatus* or *Aedes aegypti* mosquitoes, and the number of landings and blood feedings were determined.

The test material was effective against fleas for up to 15 days, and was effective against *Dermacentor variabilis* ticks for up to 9 days. It was ineffective against the initial infestation of *Rhipicephalus sanguineus* ticks, but was effective against the day 7 and day 14 re-infestation of that genus from days 8 through 16. The test material was not effective against mosquito landings on the dogs, but was effective against blood feeding.

In study 4, (MRID 481222-14), a group of 6 dogs was treated with shampoo containing 0.050% bifenthrin (providing a dose of 2.50 mg/kg). A second group served as an untreated control. Three days after treatment, hair was clipped from the treated and control dogs and *Ixodes scapularis* nymphs were confined with the hair for 48 hours. After 24 hours exposure, the test material-treated hair was 88% effective against the nymphs; after 48 hours, it was 100% effective.

In study 5 (MRID 481222-15) two groups of dogs (6 dogs/group) were infested with fleas and *R. sanguineus* ticks. One group was treated with shampoo containing 0.050% bifenthrin (providing a dose of 2.50 mg/kg); the other group served as an untreated control. The dogs were re-infested with fleas and with *A. americanum* ticks on day 7. At 2 and 11 days after treatment, hair was clipped from the treated and control dogs and *I. scapularis* nymphs were confined with the hair for 48 hours. On days 6 and 7, the dogs were exposed for two hours to *Cx. quinquefasciatus* mosquitoes, and on days 7 and 13, to *Ae. aegypti* mosquitoes. The number of mosquito landings and blood feedings were determined.

The test material was effective against the initial infestation of fleas and *R. sanguineus* ticks for up to 72 hours, but was not effective against the day 7 re-infestation of fleas. It was not effective

against the infestation of *A. americanum* ticks at 24 hours after infestation, but was effective at 48 and 72 hours after infestation. The clipped hair treated with the test material was effective against *I. scapularis* nymphs at both 24 and 48 hours. The test material was not effective at preventing mosquito landings, but was effective at preventing blood feedings.

List the treatments including untreated control: The test material groups received 5 g/kg of shampoo containing 0.025% to 0.100% bifenthrin, for a dose of 1.0 to 4.0 mg bifenthrin/kg; the control groups were not treated.

Number of replicates per treatment: 1 or 2

Number of individuals per replicate: Fleas: 100; ticks (*R. sanguineus*): 50; ticks (*A. americanum*): 50; ticks (*Ixodes scapularis*): 10; mosquitoes (*Cx. quinquefasciatus*): 25; mosquitoes (*Ae. aegypti*): 25

Length of exposure to treatment: Up to 3 days

Experimental conditions: Ambient temperature >50°F. For the clipped hair tests: <27°C and >50% RH.

Data or endpoints that were to be collected/recorded: Number of surviving fleas and ticks, number of live and dead mosquitoes, number of mosquito landings; number of mosquito blood feedings.

Statistical analyses: The method of calculating efficacy and determining statistical significance is detailed in the individual studies.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments:

A summary of results is provided in Table 1.

Study Author's Conclusions

The study author concluded that the study results support the label claims against fleas and ticks that are on the dog when treated, and also support residual claims against all four tick species that may attempt to infest the dog for at least 7, and up to 14, days after treatment. The nymphs of Lyme vector tick species are killed for at least one week after treatment. Female mosquitoes are prevented from taking a blood meal for at least one, or up to two, weeks after treatment.

Summary Data Analysis of Efficacy Data for Biphenthrin Shampoos, against Fleas, Ticks and Mosquitoes on Dogs

Study ID	Potency	Dose rate	No dogs	Mean Group Efficacy values =/>90%, on days after treatment (*re-infestation*)						
	% w/w	mg/kg		Fleas	Rhipicephalus	Dermacentor	Amblyomma	Ixodes	Culex	Aedes
155D	0.025%	1.0	3	1,2	1,2, 14 (13)					
	0.050%	2.0	3	1,2	1,2, 7 (*1*), 8 (2), 14 (*1*), 15 (2)					
	0.075%	3.0	3	1,2	1,2, 7 (*1*), 8 (2), 14 (*1*), 15 (2)					
	0.100%	4.0	3	1,2	1,2, 7 (*1*), 8 (2), 14 (*1*), 15 (2)					
162D	0.025%	1.25	6	1,2	none	none				
	0.045%	1.25	6	1,2	none	none				
	Hartz	2.25 (Pye+)	6	1,2	2					
167D	0.050%	2.5	6	1,2, 8 (*1*), 9 (2), 15 (*1*), 16 (2)	8 (*1*), 9 (2), 15 (*1*), 16 (2)				19 none	19
	0.050%	2.5	6	1,2, 9 (2)		1, 2, 8 (*1*), 9 (2)			19 none	19
	0.050%	2.5	6	1,2, 9 (2), 15 (*1*)	8 (*1*), 9 (2)				19 none	19 none
	0.050%	2.5	6	1,2		none			19 none	19 none
	Hartz	2.25 (Pye+)	6	1	8 (*1*)					
167 2D	0.075%	3.75	6					3		
178D	0.050%	2.5	6	1, 2, 3	1, 2, 3		9 (2), 10 (3)	2, 11	6, 7	7, 13

Re-infestations were on days 6 or 7 and 13 or 14

"none" indicates no efficacy values meeting threshold

Blank spaces indicate not tested

Table 1.

Reviewers Conclusions

The reviewer agrees with the study author's conclusions.

Reviewer Recommendations

Study 1 (MRID 481222-17) supported the following label claims:

Kills …Ticks for [15 days] [2 weeks]
Kills for [15 days] [2 weeks]…Ticks
Active against fleas
Active against ticks
Kills [fleas] [and] [ticks]

It did not support the following label claims:

Kills Fleas…for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas…

Study 2 (MRID 481222-18) supported the following label claims:

Active against fleas
Active against ticks
Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks

Study 3 (MRID 481222-16) supported the following label claims:

Kills Fleas [&] [Ticks] for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas [and] Ticks
Active against fleas
Active against ticks
Kills Fleas [for [15 days] [2 weeks]], Ticks [for [15 days] [2 weeks]]
Kills Fleas [and] Ticks for [15 days] [2 weeks]
Kills adult Fleas [for up to [15 days] [2 weeks]]
Kills [fleas] [and] [ticks]
Long lasting against ticks and mosquito feeding

It did not support the following label claims:

Repels mosquitoes [for up to [15 days] [2 weeks]]
Repels and prevents blood feeding by mosquitoes for up to 2 weeks (although it would support a claim of preventing blood feeding only)

Study 4 (MRID 481222-14) supported the following label claims:

Active against ticks

Kills…ticks

Study 5 (MRID 481222-15) supported the following label claims:

Active against fleas
Active against ticks
Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks]
Kills ticks that may carry Lyme disease
Long lasting against…mosquito feeding

It did not support the following label claims:

Repels and prevents blood feeding by mosquitoes for up to 2 weeks
Repels mosquitoes [for up to…[2 weeks]

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-14

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

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DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-14. Efficacy of a 0.05% Biphenthrin Shampoo Against *Ixodes scapularis* Nymphal Ticks on Dogs. Sharp, M. 2009.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Research, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	16/07/2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since the statistical methods used the statistical package in Microsoft Excel version 97 SR-1, and the user cannot validate Microsoft's proprietary code in this software.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825 CAS NO.: 82657-04-3

FORMULATION TYPE: Liquid shampoo
PRODUCT APPLICATION RATE(S): Not provided
ACTIVE INGREDIENT APPLICATION RATE(S): Not provided

PROPOSED LABEL MARKETING CLAIMS: Active against ticks
Kills…ticks

STUDY REVIEW

Purpose: The study was conducted to determine the efficacy of 0.05% bifenthrin against nymphal ticks on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test material was a shampoo containing bifenthrin (0.05% w/w). The mean group dose rate delivered to the dogs was 2.5 mg bifenthrin/kg. The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Tick (*Ixodes scapularis*), sex not reported, nymphs

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: According to the study protocol, the dogs were to be acclimated to the test facility for approximately 14 days, and were washed during the acclimation period. The animals were housed in 3 x 10 ft runs in sheltered housing units, and provided PMI nutrition 27% high protein dog food and fresh water *ad libitum*. At test start, each dog's coat was wetted with water and the test material (in the form of a shampoo containing 0.05% bifenthrin) was applied at a rate of approximately 5 g/kg. The shampoo was massaged into the coat until a substantial lather covered the entire body surface, including limbs, tail, and head. The lather was allowed to sit for 5 minutes, then removed by rinsing with water. The dogs were then blown dry.

Three days after treatment, hair was clipped from the dogs and 10 unfed *I. scapularis* nymphs were confined with the hair in vials for 48 hours. Nymph survival was recorded after 24 and 48 hours.

List the treatments including untreated control: The test material group received 5 g/kg of shampoo containing 0.05% bifenthrin, for a dose of 2.5 mg bifenthrin/kg; the control group was not treated.

Number of replicates per treatment: 1

Number of individuals per replicate: 10

Length of exposure to treatment: Up to 48 hours.

Experimental conditions: Not reported.

Data or endpoints that were to be collected/recorded: Number of surviving nymphs.

Statistical analyses: Efficacy was calculated as:

$$\frac{\text{Mean no. of live nymphs on untreated hair} - \text{mean no. of live nymphs on treated hair}}{\text{Mean no. of live nymphs on untreated hair}} \times 100$$

Individual efficacy values were calculated as percent reduction from the mean control group count. Group efficacy (mean ± std deviation) was calculated from the aggregate individual efficacy values.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments: Results are summarized in Table 1. After 24 hours exposure, the mean percent live ticks in the test material group was 10%, compared to 86% in the untreated control. Compared to the untreated control, the test material had an efficacy of 88%. After 48 hours exposure, the mean percent live ticks in the test material group was 0%, compared to 68.3% in the untreated control. Compared to the untreated control, the test material had an efficacy of 100%.

TABLE 1. Efficacy of 0.05% bifenthrin shampoo against *I. scapularis* nymphal ticks (n=10) on dogs

Control group dog nos.	Efficacy after 24 hours (test day 4)		Efficacy after 48 hours (test day 5)	
	Percent live	Percent efficacy	Percent live	Percent efficacy
411	90	--	80	--
312	100	--	70	--
392	80	--	60	--
224	80	--	70	--
448	90	--	60	--
373	70	--	70	--
mean	86 ± 9	--	68.3 ± 6.9[a]	--
Treated group dog nos.				
420	20	77	0	100
429	0	100	0	100
356	0	100	0	100
458	30	65	0	100
234	10	88	0	100
470	0	100	0	100
Mean	10 ± 11.5[b]	88 ± 13	0	100 ± 0

Data from p. 8 of 16, MRID 481222-14

[a]Calculated by the reviewer; given incorrectly as 74 ± 15% in MRID 481222-14

[b]Calculated by the reviewer; given incorrectly as 0 ± 0% in MRID 481222-14

Study Author's Conclusions

The study author did not make any conclusions.

Reviewers Conclusions

After 24 hours exposure, the mean percent live ticks in the test material group was 10%, compared to 86% in the untreated control. Compared to the untreated control, the test material had an efficacy of 88%. After 48 hours exposure, the mean percent live ticks in the test material group was 0%, compared to 68.3% in the untreated control. Compared to the untreated control, the test material had an efficacy of 100%.

Reviewer Recommendations

This study supports the following label claims:

Active against ticks
Kills…ticks

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-15

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-15. Efficacy of Biphenthrin Shampoos Against Fleas, Ticks and Mosquitoes on Dogs. Sharp, M. 2010.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Research, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	25/02/2010
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since the statistical methods used the statistical package in Microsoft Excel SP3 in Microsoft Office Professional 2003, and the user cannot validate Microsoft's proprietary code in this software.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825 CAS NO.: 82657-04-3

FORMULATION TYPE: Liquid shampoo
PRODUCT APPLICATION RATE(S): Not provided
ACTIVE INGREDIENT APPLICATION RATE(S): Not provided

PROPOSED LABEL MARKETING CLAIMS:

Active against fleas
Active against ticks
Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks]
Repels and prevents blood feeding by mosquitoes for up to 2 weeks
Repels mosquitoes [for up to…[2 weeks]]
Kills ticks that may carry Lyme disease
Long lasting against…mosquito feeding

STUDY REVIEW

Purpose: The study was conducted to determine the efficacy of 0.05% bifenthrin against fleas, ticks, and mosquitoes on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test material was a shampoo containing bifenthrin (0.05% w/w). The mean group dose rate delivered to the dogs was 2.5 mg bifenthrin/kg. The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Flea (scientific name not provided), sex not reported, adults; tick (*Rhipicephalus sanguineus*), sex not reported, adults; tick (*Amblyomma americanum*); sex not reported, adults; tick (*Ixodes scapularis*), sex not reported, nymphs; mosquito (*Aedes aegypti*), males and females, adults; mosquito (*Culex quinquefasciatus*), males and females, adults.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: According to the study protocol, the dogs were to be acclimated to the test facility for approximately 14 days, during which they were tested to assess their ability to hold a viable population of fleas and ticks. The dogs were washed with a non-insecticidal shampoo at least one day prior to the pretest infestation with the test organisms. After washing, the dogs were to be thoroughly combed to remove any residual fleas and ticks. The

animals were housed in 3 x 10 ft runs in sheltered housing units, and provided PMI nutrition 27% high protein dog food and fresh water *ad libitum*.

The dogs were allocated to groups (6 dogs/group) by body weight, and on the day before treatment were infested with 100 unfed fleas and 50 *R. sanguineus* ticks. The dogs were re-infested with new fleas and *A. americanum* ticks on day 7.

At test start, the test material group dogs were treated with the test material shampoo. According to the study protocol, each dog's coat was wetted with water and the shampoo was applied at a rate of 5 g/kg. The shampoo was massaged into the coat until a substantial lather covered the entire body surface, including limbs, tail, and head. The lather was allowed to sit for 5 minutes, then removed by rinsing with water. The dogs were then blown dry. The control group was not treated.

Flea and tick counts were made on days 1, 2, and 3 after treatment and on days 8, 9, and 10 after treatment (1, 2, and 3 days after re-infestation). The day 1, 2, 8, and 9 counts were timed body/hand counts without removing the parasites. The day 3 and 10 counts were comb counts that removed all fleas and ticks.

For the *I. scapularis* test, hair clipped from the treated and control dogs on days 3 and 12 was placed in petri dishes and 10 viable nymphs were placed in each dish. The number of live nymphs was counted after 24 and 48 hours.

For the mosquito tests, test material and control group dogs were anesthetized and confined for two hours in large modified "Gerber" type mosquito cages, each containing approximately 25 unfed mixed male and female mosquitoes. The mosquitoes that landed on the dogs during the first five minutes of exposure were counted. After two hours, the dogs were removed and the live and dead mosquitoes in the cage were counted. The female mosquitoes were squashed on moist absorbent white paper to detect the presence of blood. *Cx. quinquefasciatus* were used in the test on days 6 and 7, and *Ae. aegypti* were used on days 7 and 13.

List the treatments including untreated control: The test material group received 5 g/kg of shampoo containing 0.05% bifenthrin, for a dose of 2.5 mg bifenthrin/kg; the control group was not treated.

Number of replicates per treatment: 1

Number of individuals per replicate: Fleas: 100; ticks (*R. sanguineus*): 50; ticks (*A. americanum*): 50; ticks (*Ixodes scapularis*): 10; mosquitoes (*Cx. quinquefasciatus*): 25; mosquitoes (*Ae. aegypti*): 25

Length of exposure to treatment: Up to 3 days

Experimental conditions: Ambient temperature >50°F. For the clipped hair test: <27°C and >50% RH.

Data or endpoints that were to be collected/recorded: Number of surviving fleas and ticks, number of live and dead mosquitoes, number of mosquito landings, number of mosquito blood feedings.

Statistical analyses: For the flea, *R. sanguineus*, and *A. americanum* tests, efficacy was calculated as:

$$\frac{\text{Mean no. of live ticks/fleas on untreated dogs} - \text{mean no. of live fleas/ticks on treated dogs}}{\text{Mean no. of live ticks/fleas on untreated dogs}} \times 100$$

For the I. *scapularis* test, efficacy was calculated as:

$$\frac{\text{Mean no. of live nymphs on untreated hair} - \text{mean no. of live nymphs on treated hair}}{\text{Mean no. of live nymphs on untreated hair}} \times 100$$

For the mosquito tests, efficacy was calculated as:

Mortality:

$$\frac{\text{Mean no. of live mosquitoes from untreated dogs} - \text{mean no. of live mosquitoes from treated dogs}}{\text{Mean no. of live mosquitoes from untreated dogs}} \times 100$$

Reduction in blood feeding:

$$\frac{\text{Mean no. of blood fed mosquitoes from untreated dogs} - \text{mean no. of blood fed mosquitoes from treated dogs}}{\text{Mean no. of blood fed mosquitoes from untreated dogs}} \times 100$$

Individual efficacy values were calculated as percent reduction from the mean control group count. Group efficacy (mean ± std deviation) was calculated from the aggregate individual efficacy values. Significant differences in flea and tick counts between the treated and control dogs were determined by Student's "t" test, using the statistical program in Microsoft Excel SP3 in Microsoft Office Professional 2003. The significance level was 5%.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments:

Results for fleas are summarized in Table 1. Compared to the untreated control, the test material was ≥99% effective against fleas for the first three days after treatment, and ineffective thereafter.

Table 1.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Flea Counts

Days after Treatment		0	1		2		3		8		9		10	
Dog no.	Group		No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
380	C		28		20		18		30		29		28	
462	C		23		19		23		30		34		30	
416	C		18		22		18		30		28		30	
421	C		30		35		36		35		37		35	
392	C		27		24		28		31		38		37	
381	C		26		39		29		55		46		50	
Mean			25.3		26.5		25.3		35.2		35.3		35.0	
+/- S.D.			4.3		8.4		7.0		9.9		6.6		8.1	
467	A		0	100%	0	100%	0	100%	11	69%	17	52%	11	69%
422	A		0	100%	0	100%	0	100%	22	37%	21	41%	18	49%
225	A		0	100%	0	100%	0	100%	16	55%	4	89%	1	97%
428	A		1	96%	0	100%	0	100%	14	60%	12	66%	7	80%
373	A		0	100%	0	100%	0	100%	20	43%	9	75%	6	83%
359	A		0	100%	0	100%	0	100%	6	83%	12	66%	8	77%
Mean			0.2	99%	0.0	100%	0.0	100%	14.8	58%	12.5	65%	8.5	76%
+/- S.D.			0.4	2%	0.0	0%	0.0	0%	5.9	17%	6.0	17%	5.7	16%

SVR 178D

A is the treated group, C is the untreated control.

Results for ticks are summarized in Table 2. Compared to the untreated controls, the test material was ≥98% effective against ticks for the first three days after treatment, was not effective on day 8 (one day after re-infestation), and ≥93% effective on days 9 and 10.

Table 2.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Tick Counts

Days after Treatment		Tick	0	1		2		3		8		9		10	
Dog no.	Group	Species		No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
		R.s.								*A.a.*					
380	C			35		24		26		17		19		17	
462	C			21		25		22		14		15		8	
416	C			11		11		9		12		10		8	
421	C			9		13		10		13		11		11	
392	C			24		25		22		11		15		12	
381	C			22		30		30		18		12		10	
Mean				20.3		21.3		19.8		13.8		13.7		11.0	
+/- S.D.				9.5		7.6		8.5		2.3		3.3		3.3	
467	A			3	86%	1	97%	0	100%	12	13%	1	93%	1	91%
422	A			0	100%	0	100%	0	100%	4	71%	1	93%	1	91%
225	A			0	100%	0	100%	0	100%	1	93%	0	100%	0	100%
428	A			0	100%	0	100%	0	100%	3	78%	2	85%	1	91%
373	A			0	100%	0	100%	0	100%	4	71%	0	100%	0	100%
359	A			0	100%	0	100%	0	100%	3	78%	2	85%	1	91%
Mean				0.5	98%	0.2	99%	0.0	100%	4.5	67%	1.0	93%	0.7	94%
+/- S.D.				1.2	6%	0.4	1%	0.0	0%	3.8	28%	0.9	7%	0.5	5%

SVR 178D Infestations were with 50 ticks

A is the treated group, C is the untreated control.

Results for *I. scapularis* nymphs on the hair clipped on day 2 (3 days after treatment) are summarized in Table 3. Compared to the untreated controls, the test material-treated hair was 95% effective against the nymphs at day 3, and 100% effective at day 4.

Table 3.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs
Lyme Tick Nymph / *Ixodes scapularis* in Vitro Evaluation on Day 2

Day of Study		24 hours (day 3)		48 hours (day 4)	
Dog no	Group	% live	%effic	# live	%effic
380	C	100%		90%	
462	C	90%		80%	
416	C	100%		90%	
421	C	80%		60%	
392	C	100%		70%	
381	C	80%		80%	
Mean		92%		78%	
+/- S.D.		10%		12%	
467	A	20%	78%	0%	100%
422	A	0%	100%	0%	100%
225	A	10%	89%	0%	100%
428	A	0%	100%	0%	100%
373	A	0%	100%	0%	100%
359	A	0%	100%	0%	100%
Mean		5%	95%	0%	100%
+/- S.D.		8%	9%	0%	0%

SVR 178D
A is the treated group, C is the untreated control.

Results for *I. scapularis* nymphs on the hair clipped on day 11 (12 days after treatment) are summarized in Table 4. Compared to the untreated control, the test material-treated hair was 93% effective against the nymphs on day 12, and 100% effective on day 13.

Table 4.

Day of Study		24 hours (day 12)		48 hours (day 13)	
Dog no	Group	% live	%effic	# live	%effic
380	C	90%		90%	
462	C	100%		100%	
416	C	89%		90%	
421	C	100%		100%	
392	C	90%		90%	
381	C	80%		80%	
Mean		91%		92%	
+/- S.D.		8%		8%	
467	A	0%	100%	0%	100%
422	A	20%	78%	10%	100%
225	A	20%	78%	10%	100%
428	A	0%	100%	0%	100%
373	A	0%	100%	0%	100%
359	A	0%	100%	0%	100%
Mean		7%	93%	3%	100%
+/- S.D.		10%	11%	5%	0%

SVR 178D
A is the treated group, C is the untreated control.

Results for the *Cx. quinquefasciatus* test are summarized in Table 5. The efficacy of the test material at preventing landings on the dogs was 100% on all but one dog, which brought the overall mean down to 84%. The test material did not effectively induce mosquito mortality during the two-hour exposure. However, it was 94% effective at reducing blood feeding by the mosquitoes.

Table 5.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Culex quinquefasciatus

Days after Treatment		0			Days 6 * & 7 #			
Group	Dog no		% landings	% effic	% live	%effic	% fed	%effic
C	380*		4%		100%		45%	
C	462*		7%		92%		90%	
C	416*		0%		93%		65%	
C	421#		4%		100%		85%	
C	392#		3%		100%		100%	
C	381#		4%		100%		45%	
	Mean		4%		97%		72%	
	+/- S.D.		2%		4%		23%	
A	467*	T	0%	100%	96%	1%	27%	63%
A	422*	R	0%	100%	85%	13%	0%	100%
A	225*	E	0%	100%	79%	19%	0%	100%
A	428#	A	0%	100%	96%	1%	0%	100%
A	373#	T	4%	3%	100%	-3%	0%	100%
A	359#		0%	100%	96%	1%	0%	100%
	Mean		1%	84%	92%	5%	4%	94%
	+/- S.D.		1%	40%	8%	8%	11%	15%

SVR 178D * Day 6 # Day 7

A is the treated group, C is the untreated control.

Results for the *Ae. aegypti* test are summarized in Table 6. The test material was not effective at preventing landings on the dogs or at inducing mosquito mortality during the two-hour exposure. However, it was 93% effective at reducing blood feeding by the mosquitoes.

Table 6.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Aedes aegypti

Days after Treatment		0			Day 7 & 13#			
Group	Dog no		% landings	% effic	% live	%effic	% fed	%effic
C	421*		3%		97%		45%	
C	392*		4%		100%		85%	
C	381*		0%		96%		82%	
C	380#		3%		100%		73%	
C	462#		7%		100%		83%	
C	416#		3%		100%		69%	
	Mean		4%		98%		71%	
	+/- SD		2%		2%		22%	
A	428*	T	0%	100%	85%	13%	0%	100%
A	373*	R	0%	100%	96%	1%	0%	100%
A	359*	E	0%	100%	92%	6%	0%	100%
A	467#	A	3%	5%	100%	-2%	29%	60%
A	422#	T	3%	5%	100%	-2%	0%	100%
A	225#		7%	-89%	100%	-2%	0%	100%
	Mean		2%	37%	96%	2%	5%	93%
	+/- s.d.		3%	77%	6%	6%	12%	16%

SVR 178D * Day 7 # Day 13

A is the treated group, C is the untreated control.

The mean efficacy of the test material in each of the tests is summarized in Table 7.

Table 7.
Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs
Group Mean Efficacy against Flea, Ticks, Lyme Tick Nymphs and Mosquitoes

Parasite	0	Days after treatment										
		1	2	3	4	6 & 7	8	9	10	12	13	7 & 13
Fleas	T	99%	100%	100%			58%	65%	76%			
Ticks	R	98%	99%	100%			67%	93%	94%			
	T											
Lyme ticks												
day 2				95%	100%							
day 11										93%	100%	
Mosquitoes *												
Culex repelled						84%						
Culex no feed						94%						
Aedes repelled												37%
Aedes no feed												93%

SVR 178D Efficacy values equaling or exceeding EPA claim support threshold (90%)

Statistical analyses showed that the test material significantly reduced the number of fleas and ticks throughout the test (Table 8).

Table 8.
Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs
Significance of Apparent Differences in Flea and Tick Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	8	9	15	16
Comparing groups						
Fleas						
C						
vs	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.002**	**< 0.0001**	**< 0.0001**
A						
Ticks						
C						
vs	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0005**	**< 0.0001**	**< 0.0001**
A						

SVR 178D Statistically significant differences are in **"bold"** type
Indicates group with significantly lower parasite counts
A is the treated group, C is the untreated control.

Study Author's Conclusions

The study author concluded that group efficacy against fleas and *R. sanguineus* ticks was 98-100% at 24, 48, and 72 hours after treatment. After re-infestation on day 7, the test material provided 58-76% efficacy against fleas at 24, 48, and 72 hours and 93-94% efficacy against *A. americanum* ticks at 48 and 72 hours. Efficacy was 93-100% against I. *scapularis* nymphs exposed on days 2 and 11 to clipped hair from treated dogs. The test material prevented *Culex* mosquitoes from landing on the treated dogs on days 6 and 7, and was similarly effective against *Aedes* mosquitoes on day 7 but not day 13. The test material was 93-100% effective at preventing blood feeding by the female mosquitoes of both species.

Reviewers Conclusions

The reviewer agrees with the study author's conclusions. Although the overall mean for *Culex* landings on the dogs was only 84%, the test material was 100% effective on all but one dog. The study author concluded that the test material was 93-100% effective at preventing blood feeding by mosquitoes; the actual results provided showed 93 to 94% efficacy.

Reviewer Recommendations

This study supports the following label claims:

Active against fleas
Active against ticks
Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks]
Kills ticks that may carry Lyme disease
Long lasting against…mosquito feeding

It does not support the following label claims:

Repels and prevents blood feeding by mosquitoes for up to 2 weeks
Repels mosquitoes [for up to…[2 weeks]]

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-16

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-16. Efficacy of Biphenthrin Shampoos Against Fleas, Ticks and Mosquitoes on Dogs. Sharp, M. 2009.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Research, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	16/07/2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since the statistical methods used the statistical package in Microsoft Excel version 97 SR-1, and the user cannot validate Microsoft's proprietary code in this software.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825 CAS NO.: 82657-04-3 FORMULATION TYPE: Liquid shampoo

	PRODUCT APPLICATION RATE(S): Not provided ACTIVE INGREDIENT APPLICATION RATE(S): Not provided
PROPOSED LABEL MARKETING CLAIMS:	Kills Fleas [&] [Ticks] for [15 days] [2 weeks] Kills for [15 days] [2 weeks] Fleas [and] Ticks Active against fleas Active against ticks Kills Fleas [for [15 days] [2 weeks]], Ticks [for [15 days] [2 weeks]] Kills Fleas [and] Ticks for [15 days] [2 weeks] Kills adult Fleas [for up to [15 days] [2 weeks]] Kills [fleas] [and] [ticks] Repels and prevents blood feeding by mosquitoes for up to 2 weeks Repels mosquitoes [for up to [15 days [2 weeks]] Long lasting against ticks and mosquito feeding

STUDY REVIEW

Purpose: The study was conducted to determine the efficacy of 0.05% bifenthrin against fleas, ticks, and mosquitoes on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test material was a shampoo containing bifenthrin (0.05% w/w). The mean group dose rate delivered to the dogs was 2.5 mg bifenthrin/kg. The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Flea (scientific name not provided), sex not reported, adults; tick (*Rhipicephalus sanguineus*), sex not reported, adults; tick (*Dermacentor variabilis*); sex not reported, adults; mosquito (*Aedes aegypti*), males and females, adults; mosquito (*Culex quinquefasciatus*), males and females, adults.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: The test consisted of two test material groups and two control groups. Information on how the dogs were acclimated, housed, cared for, or fed was not provided. The dogs were allocated to groups (6 dogs/group) by body weight, and on the day before treatment were infested with 100 unfed fleas. One each of the treated and control groups was infested with 50 *R. sanguineus* ticks, and the other was infested with 50 *D.variabilis* ticks. The

dogs were re-infested with the appropriate test organisms on days 7 and 14. Additionally, the dogs in one test material group and one control group were re-infested with fleas only on day 21.

No description was provided for how the test material was applied to the treated dogs. The control group was not treated.

Flea and tick counts were made on days 1, 2, 8, 9, 15, 16, 22, and 23. The day 1, 8, 15, and 22 counts were timed body/hand counts without removing the parasites. The day 2, 9, 16, and 23 counts were comb counts that removed all fleas and ticks.

Mosquito tests were conducted on day 19. Test material and control group dogs were anesthetized and confined for one hour in large modified "Gerber" type mosquito cages, each containing approximately 25 unfed mixed male and female mosquitoes. The mosquitoes that landed on the dogs during the first five minutes of exposure were counted. After one hour, the dogs were removed and the live and dead mosquitoes in the cage were counted. The female mosquitoes were squashed on moist absorbent white paper to detect the presence of blood.

List the treatments including untreated control: The test material group received 5 g/kg of shampoo containing 0.05% bifenthrin, for a dose of 2.5 mg bifenthrin/kg; the control group was not treated.

Number of replicates per treatment: 2

Number of individuals per replicate: Fleas: 100; ticks (*R. sanguineus*): 50; ticks (*D. variabilis*): 50; mosquitoes (*Cx. quinquefasciatus*): 25; mosquitoes (*Ae. aegypti*): 25

Length of exposure to treatment: Up to 2 days

Experimental conditions: Not provided.

Data or endpoints that were to be collected/recorded: Number of surviving fleas and ticks, number of live and dead mosquitoes, number of mosquito blood feedings

Statistical analyses: Individual efficacy values were calculated as percent reduction from the mean control group count. Group efficacy (mean ± std deviation) was calculated from the aggregate individual efficacy values. Significant differences in flea and tick counts between the treated and control dogs were determined by Student's "t" test, using the statistical program in Microsoft Excel version 97 SR-1. The significance level was 5%.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments: Results for fleas are summarized in Table 1. Compared to the untreated controls, results for the combined test material groups showed the test material was effective against fleas for up to 15 days.

Table 1.

Efficacy of Bifenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Flea Counts

Days after Treatment			0	1		2		8		9		16		16		22		23	
Dog no.	Group			No.	Eff %	No	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
411	C1			5		5		8		2		12		11		13		12	
312	C1			19		18		19		17		13		15		12		18	
502	C1			29		20		22		20		20		19		17		20	
224	C1			12		12		14		16		19		17		9		7	
448	C1			14		13		20		19		18		18		13		12	
373	C1			32		29		30		30		30		33		21		25	
Mean				18.5		16.2		18.8		17.3		18.7		18.5		14.2		15.7	
+/- S.D.				10.4		8.2		7.4		9.0		6.4		7.6		4.2		8.8	
361	C2			31		25		26		27		19		18					
351	C2			23		17		18		22		29		30					
461	C2			14		16		21		19		16		16					
378	C2			20		14		20		23		28		28					
449	C2			25		35		30		37		33		36					
222	C2			32		33		27		19		22		20					
Mean				24.7		23.5		25.0		24.5		24.8		25.0					
+/- S.D.				7.0		9.4		7.4		8.8		5.0		7.5					
Mean	C1 & C2			21.6		19.8		22.1		20.9		21.8		21.8					
+/- S.D.				9.9		9.2		7.9		8.5		6.8		7.9					
420	A1	T	0	0	100%	0	100%	0	100%	0	100%	0	100%	2	94%	7	51%	6	62%
429	A1	R	0	0	100%	0	100%	0	100%	0	100%	0	100%	2	94%	22	-65%	10	38%
358	A1	E	0	0	100%	0	100%	0	100%	0	100%	0	100%	1	97%	17	-20%	5	68%
458	A1	A	4	4	78%	4	75%	6	100%	0	100%	0	100%	1	97%	6	58%	3	81%
234	A1	T	2	2	89%	3	81%	0	100%	0	100%	0	100%	2	94%	8	44%	7	55%
470	A1		0	0	100%	0	100%	5	73%	8	55%	4	87%	3	91%	20	-41%	23	-47%
Mean				1.0	95%	1.2	93%	3.8	90%	1.0	94%	0.7	98%	1.8	94%	13.3	6%	9.0	43%
+/- S.D.				1.7	9%	1.8	11%	2.9	11%	2.4	14%	1.6	5%	0.8	2%	7.1	59%	7.2	46%
421	A2	T	0	0	100%	0	100%	0	100%	0	100%	0	100%	0	100%				
424	A2	R	0	0	100%	0	100%	4	84%	0	100%	3	88%	5	80%				
425	A2	E	1	95%	0	100%	7	72%	4	84%	4	84%	4	84%					
328	A2	A	1	96%	1	96%	1	96%	0	100%	1	96%	2	92%					
464	A2	T	0	100%	0	100%	7	72%	3	89%	11	66%	12	52%					
456	A2		2	92%	3	87%	6	76%	0	100%	5	80%	5	80%					
Mean				0.7	97%	0.7	97%	4.2	84%	1.2	95%	4.0	84%	4.7	81%				
+/- S.D.				0.5	3%	1.2	5%	3.1	12%	1.8	7%	3.9	16%	4.1	16%				
Mean	A1 & A2			0.8	98%	0.9	95%	2.5	90%	1.1	95%	2.3	91%	3.3	88%				
+/- S.D.				1.3	7%	1.5	9%	3.0	13%	2.1	11%	3.3	13%	3.2	13%				
347	D	T	1	50%	0	100%	0	100%	0	100%	5	50%	4	84%					
453	D	R	3	85%	7	70%	15	41%	11	59%	10	60%	10	60%					
427	D	E	10	59%	8	66%	17	33%	19	22%	21	15%	22	12%					
406	D	A	1	90%	1	96%	21	17%	15	27%	24	3%	26	-4%					
368	D	T	0	100%	0	100%	8	68%	8	86%	8	68%	7	72%					
422	D		0	100%	0	100%	24	5%	21	14%	22	11%	20	20%					
Mean				2.5	90%	2.7	89%	14.2	44%	12.9	51%	15.0	40%	14.8	41%				
+/- S.D.				3.8	16%	3.8	16%	8.4	35%	8.9	36%	8.2	33%	9.0	36%				

SVR 1870 Infestations were with 100 fleas

A1 & A2 are the treated groups, C1 & C2 are the untreated controls.

The group means are given in Table 2. Although Table 2 does not include the result, Table 1 indicates that the efficacy for the combined treated groups A1 & A2 against fleas was 91% at day 15.

Table 2.
Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs
Group Mean Efficacy against Fleas

Group	Dose rate mg/kg	0	Days after treatment 1	2	8	9	15	16	22	23
	Biphenthrin									
A1	2.50	T	95%	93%	96%	94%	98%	94%	6%	43%
A2	2.50	R E	97%	97%	84%	96%	84%	81%		
A1 & A2	2.50	A T	96%	96%	90%	95%		88%		
	Pyrethrins									
D	26.80		90%	89%	44%	51%	40%	41%		

SVR 167D — Efficacy values equaling or exceeding EPA claim support threshold (90%)

A1 & A2 are the treated groups, D is a positive control.

Statistical significance for the flea counts is shown in Table 3. Compared to the untreated controls, the test material significantly reduced the number of fleas on the treated dogs for up to 16 days.

Table 3.
Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs
Significance of Apparent Differences in Flea Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	8	9	15	16	22	23
Comparing groups								
C1 *vs* C2	> 0.2	> 0.1	> 0.1	> 0.1	> 0.1	> 0.9	NA	NA
C1 & C2 *vs* A1 & A2	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**	C1 (only) > 0.8 A1 (only)	C1 (only) > 0.1 A1 (only)
A1 *vs* A2	> 0.7	> 0.5	> 0.05	> 0.8	> 0.05	> 0.1	NA	NA
C1 & C2 *vs* D	**< 0.0001**	**< 0.0001**	> 0.05	> 0.05	> 0.05	> 0.1	NA	NA
A1 & A2 *vs* D	> 0.1	> 0.1	**< 0.001**	**< 0.0001**	**< 0.0005**	**< 0.001**	NA	NA

SVR 167D — Indicates group with significantly lower parasite counts
Statistically significant differences are "**bold**"

Results for ticks are summarized in Table 4. Compared to the untreated controls, the test material was effective against *Dermacentor variabilis* ticks for up to 9 days. It was ineffective against the initial infestation of *Rhipicephalus sanguineus* ticks, but was effective against the day 7 and day 14 re-infestation of that genus from days 8 through 16.

Table 4.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Tick Counts

Days after Treatment		Tick		0		1		2		8		9		15		16	
Dog no.	Group	Species		No.	Eff %	No.	Eff %			No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
411	C1	R.s.	INFEST	8		7		INFEST		6		3		INFEST	12		10	
312	C1	R.s.		11		9				8		7			24		20	
392	C1	R.s.		18		14				13		11			18		16	
224	C1	R.s.		17		12				10		7			13		12	
448	C1	R.s.		10		12				3		3			12		12	
373	C1	R.s.		26		17				24		19			24		27	
Mean				15.0		11.8				10.7		8.3			17.2		16.2	
+/- S.D.				6.7		3.5				7.4		6.0			5.7		6.4	
361	C2		INFEST	25		27		INFEST		36		33		INFEST	13		19	
351	C2			25		20				11		15			21		10	
461	C2			13		15				22		21			7		12	
378	C2			28		20				21		15			28		27	
449	C2			36		33				16		16			30		30	
222	C2			20		20				17		7			13		15	
Mean				24.5		22.5				20.6		17.8			18.3		20.3	
+/- S.D.				7.7		6.4				8.5		8.7			8.8		6.9	
420	A1	R.s	INFEST TREAT	0	100%	0	100%	INFEST		0	100%	0	100%	INFEST	0	100%	1	94%
429	A1	R.s		0	100%	0	100%			0	100%	0	100%		0	100%	3	81%
356	A1	R.s		1	93%	3	75%			0	100%	0	100%		0	100%	0	100%
458	A1	R.s		0	100%	4	68%			0	100%	0	100%		0	100%	1	94%
234	A1	R.s.		3	80%	2	83%			0	100%	0	100%		0	100%	1	94%
470	A1	R.s		8	47%	8	32%			2	88%	2	71%		1	94%	1	94%
Mean				2.0	87%	2.8	76%			0.3	98%	0.3	95%		0.2	99%	1.2	93%
+/- S.D.				3.2	21%	3.0	25%			0.8	5%	0.8	12%		0.4	2%	1.0	6%
421	A2	D.v	INFEST TREAT	0	100%	0	100%	INFEST		0	100%	0	100%	INFEST	0	100%	1	95%
424	A2	D.v		0	100%	0	100%			0	100%	0	100%		0	100%	0	100%
425	A2	D.v		0	100%	0	100%			2	88%	2	71%		8	67%	4	80%
328	A2	D.v		5	80%	2	91%			0	100%	0	100%		0	100%	2	90%
464	A2	D.v		0	100%	0	100%			1	94%	1	86%		9	51%	10	51%
408	A2	D.v.		4	84%	1	96%			0	100%	0	100%		8	56%	7	68%
Mean				1.5	94%	0.5	98%			0.5	97%	0.5	93%		3.8	79%	4.0	80%
+/- S.D.				2.3	10%	0.8	4%			0.8	5%	0.8	12%		4.3	24%	3.8	19%
347	D	R.s.	INFEST TREAT	0	100%	0	100%	INFEST		0	100%	0	100%	INFEST	0	100%	0	100%
483	D	R.s.		1	98%	0	100%			0	100%	0	100%		8	56%	9	56%
427	D	R.s.		8	67%	10	56%			0	100%	0	100%		12	36%	16	28%
406	D	R.s.		3	88%	4	82%			4	76%	3	57%		6	67%	6	70%
368	D	R.s.		4	84%	3	87%			2	86%	2	71%		4	78%	4	80%
422	D	R.s.		6	76%	6	73%			4	76%	2	71%		20	-9%	18	11%
Mean				3.7	85%	3.8	83%			1.7	90%	1.2	83%		8.3	55%	8.7	57%
+/- S.D.				3.0	12%	3.8	17%			2.0	12%	1.3	19%		7.0	38%	6.8	33%

SVR 167D Infestations were with 50 ticks

A1 & A2 are the treated groups, C1 & C2 are the untreated controls.

R.s. = *Rhipicephalus sanguineus*

D.v = *Dermacentor variabilis*

The group means are given in Table 5.

Table 5.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Group Mean Efficacy against Ticks

Group	Dose rate mg/kg		Days after treatment 0	1	2	8	9	15	16
	Biphenthrin								
A1 (*R.s.*)	2.50	T		87%	76%	98%	95%	99%	93%
A2 (*D.v.*)	2.50	R E A		94%	98%	97%	93%	79%	80%
	Pyrethrins								
D (*R.s.*)	26.80			85%	83%	90%	83%	55%	57%

SVR 167D — **Efficacy values equaling or exceeding EPA claim support threshold (90%)**

A is the treated group, C is the untreated control. D is a positive control.
R.s. = *Rhipicephalus sanguineus*
D.v = *Dermacentor variabilis*

Statistical significance for the tick counts is shown in Table 6. Compared to the untreated controls, each of the test material groups had significantly fewer ticks for up to 16 days.

Table 6.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Significance of Apparent Differences in Tick Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	8	9	15	16
Comparing groups						
C1 (*R.s.*) vs C2 (*D.v.*)	**< 0.05**	**< 0.01**	**< 0.05**	> 0.05	> 0.7	> 0.3
A1 (*R.s.*) vs C1 (*R.s.*)	**< 0.002**	**< 0.001**	**< 0.002**	**< 0.01**	**< 0.001**	**< 0.001**
A2 (*D.v.*) vs C2 (*D.v.*)	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.001**	**< 0.0001**	**< 0.0001**
D (*R.s.*) vs C1 (*R.s.*)	**< 0.005**	**< 0.005**	**< 0.01**	**< 0.02**	**< 0.05**	> 0.05
A1 (*R.s.*) vs D (*R.s.*)	> 0.3	> 0.6	> 0.8	> 0.1	**< 0.02**	**< 0.05**

SVR 167D — Indicates group with significantly lower parasite counts

Statistically significant differences are "**bold**"

A1 & A2 are the treated groups, C1 & C2 are the untreated controls. D is a positive control.
R.s. = *Rhipicephalus sanguineus*
D.v = *Dermacentor variabilis*

Results for the *Cx. quinquefasciatus* mosquito test are summarized in Table 7. The test material did not effectively induce mosquito mortality during the one-hour exposure. However, it was 94% effective at reducing blood feeding by the mosquitoes on day 19. The test material was not effective at preventing mosquito landings (results not shown in table).

Table 7.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Culex quinquefasciatus

Days after Treatment		0	Day 19			
Group	Dog no		% live	%effic	% fed	%effic
C	392		100%		20%	
C	224		96%		46%	
C	373		100%		46%	
	Mean		99%		37%	
	+/- SD		3%		15%	
A	420	T	89%	10%	0%	100%
A	429	R	92%	7%	0%	100%
A	356	E	93%	6%	7%	82%
	Mean	A	91%	7%	2%	**94%**
	+/- s.d.	T	2%	2%	4%	10%

SVR 167D

A is the treated group, C is the untreated control.

Results for the *Ae. aegypti* test are summarized in Table 8. The test material did not effectively induce mosquito mortality during the one-hour exposure. However, it was 96% effective at reducing blood feeding by the mosquitoes on day 19. The test material was not effective at preventing mosquito landings (results not shown in table).

Table 8.

Efficacy of Biphenthrin Shampoos against Fleas, Ticks and Mosquitoes on Dogs

Aedes aegypti

Days after Treatment		0	Day 19			
Group	Dog no		% live	%effic	% fed	%effic
C	361		100%		35%	
C	449		100%		33%	
C	222		100%		38%	
	Mean		100%		36%	
	+/- SD		0%		3%	
A	458	T	93%	7%	0%	100%
A	234	R	100%	0%	0%	100%
A	470	E	100%	0%	0%	100%
A	424	A	100%	0%	5%	86%
	Mean	T	98%	2%	1%	**96%**
	+/- s.d.		3%	3%	3%	7%

SVR 167D

A is the treated group, C is the untreated control.

Study Author's Conclusions

The study author concluded that the test results support a claim against fleas for up to three weeks, a claim against *D. variabilis* ticks for up to two weeks, a claim against *R. sanguineus* for up to 9 days, and a claim against mosquitoes taking a blood meal for up to 19 days after treatment.

Reviewers Conclusions

The reviewer agrees with the study author's conclusions.

Reviewer Recommendations

This study supports the following label claims:

Kills Fleas [&] [Ticks] for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas [and] Ticks
Active against fleas
Active against ticks
Kills Fleas [for [15 days] [2 weeks]], Ticks [for [15 days] [2 weeks]]
Kills Fleas [and] Ticks for [15 days] [2 weeks]
Kills adult Fleas [for up to [15 days] [2 weeks]]
Kills [fleas] [and] [ticks]
Long lasting against ticks and mosquito feeding

It does not support the following label claims:

Repels mosquitoes [for up to [15 days] [2 weeks]]
Repels and prevents blood feeding by mosquitoes for up to 2 weeks (although it would support a claim of preventing blood feeding only)

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-17

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-17. Efficacy of Four Biphenthrin Shampoos Against Fleas and Ticks on Dogs. Sharp, M. 2009.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Research, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	06/04/2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since the statistical methods used the statistical package in Microsoft Excel version 97 SR-1, and the user cannot validate Microsoft's proprietary code in this software.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825 CAS NO.: 82657-04-3 FORMULATION TYPE: Liquid shampoo

PRODUCT APPLICATION RATE(S): Not provided
ACTIVE INGREDIENT APPLICATION RATE(S): Not provided

PROPOSED LABEL MARKETING CLAIMS:

Kills Fleas [&] Ticks for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas [and] Ticks
Active against fleas
Active against ticks
Kills [fleas] [and] [ticks]

STUDY REVIEW

Purpose: The study was conducted to determine the efficacy of 0.025%, 0.050%, 0.075%, and 0.100% bifenthrin against fleas and ticks on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test materials were four shampoos containing bifenthrin (0.025%, 0.050%, 0.075%, or 0.100% w/w, delivering dose rates of 1.0, 2.0, 3.0, and 4.0 mg bifenthrin/kg, respectively). The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Flea (*Ctenocephalides felis*), sex not provided, adults; tick (*Rhipicephalus sanguineus*), sex not reported, adults

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: According to the study protocol, the dogs were to be acclimated to the test facility for approximately 14 days, and were washed during the acclimation period. The animals were housed in 3 x 10 ft runs in sheltered housing units, and provided PMI nutrition 27% high protein dog food and fresh water *ad libitum*.

The dogs were allocated to groups (3 dogs/group) by body weight, and on the day before treatment were infested with 100 unfed fleas and 50 unfed tieks. All groups were re-infested twice more at approximately weekly intervals.

At test start, each dog in the treated groups had its coat wetted with water and the appropriate test material (in the form of a shampoo containing 0.025%, 0.050%, 0.075%, or 0.100% % bifenthrin) was applied at a rate of approximately 4 g/kg. The shampoo was massaged into the coat until a substantial lather covered the entire body surface, including limbs, tail, and head. The lather was allowed to sit for 5 minutes, then removed by rinsing with water. The dogs were then blown dry. The control group was not treated.

Flea and tick counts were made on days 1 and 2 after treatment, on days 7 and 8 after treatment (1 and 2 days after re-infestation on day 6), and on days 14 and 15 (1 and 2 days after the second re-infestation on day 13). The day 1 counts were timed body/hand counts without removing the parasites; the succeeding counts were comb counts that removed all fleas and ticks.

List the treatments including untreated control: The test material groups received 4 g/kg of shampoo containing 0.025%, 0.050%, 0.075%, or 0.100% % bifenthrin, providing doses of 1.0, 2.0, 3.0, and 4.0 mg bifenthrin/kg, respectively ; the control group was not treated.

Number of replicates per treatment: 1

Number of individuals per replicate: Fleas: 100; ticks: 50

Length of exposure to treatment: Up to 2 days.

Experimental conditions: Ambient temperature >50°F.

Data or endpoints that were to be collected/recorded: Number of surviving fleas and ticks.

Statistical analyses: Efficacy was calculated as:

$$\frac{\text{Mean no. of live ticks/fleas on untreated dogs} - \text{mean no. of live ticks/fleas on treated dogs}}{\text{Mean no. of live ticks/fleas on untreated dogs}} \times 100$$

Individual efficacy values were calculated as percent reduction from the mean control group count. Group efficacy (mean ± std deviation) was calculated from the aggregate individual efficacy values.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments: Results for fleas are summarized in Table 1. All four test material concentrations provided 100% control of fleas at 24 hours and 48 hours after treatment. None of the test materials provided acceptable control (>90%) at the succeeding time points.

Table 1.

Efficacy of Four Biphenthrin Shampoos against Fleas and Ticks on Dogs

Flea Counts

Days after Treatment		0	1		2		7		8		14		15	
Dog no.	Group		No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
424	A		37		35		29		38		31		40	
381	A		44		32		39		30		34		26	
312	A		31		24		22		19		26		27	
Mean			37.3		30.3		30.0		29.0		30.3		31.0	
+/- S.D.			6.5		5.7		8.5		9.5		4.0		7.8	
425	B	T	0	100%	0	100%	3	90%	0	100%	5	84%	9	74%
301	B	R	0	100%	0	100%	12	60%	8	72%	10	67%	11	65%
368	B	E	0	100%	0	100%	12	60%	10	66%	20	34%	13	58%
Mean		A	0.0	100%	0.0	100%	9.0	70%	6.0	79%	11.7	62%	10.7	66%
+/- S.D.		T	0.0	0%	0.0	0%	5.2	17%	5.3	18%	7.6	25%	2.5	8%
425	C	T	0	100%	0	100%	1	97%	0	100%	0	100%	5	84%
301	C	R	0	100%	0	100%	34	-13%	11	62%	9	70%	10	68%
368	C	E	0	100%	0	100%	16	47%	4	86%	12	60%	11	65%
Mean		A	0.0	100%	0.0	100%	17.0	43%	5.0	83%	7.0	77%	8.7	72%
+/- S.D.		T	0.0	0%	0.0	0%	16.5	55%	5.6	19%	6.2	21%	3.2	10%
420	D	T	0	100%	0	100%	15	50%	5	83%	19	37%	12	61%
412	D	R	0	100%	0	100%	22	27%	12	59%	18	41%	13	58%
356	D	E	0	100%	0	100%	15	50%	7	76%	16	47%	6	81%
Mean		A	0.0	100%	0.0	100%	17.3	42%	8.0	72%	17.7	42%	10.3	67%
+/- S.D.		T	0.0	0%	0.0	0%	4.0	13%	3.6	12%	1.5	5%	3.8	12%
420	E	T	0	100%	0	100%	32	-7%	10	66%	12	60%	19	39%
412	E	R	0	100%	0	100%	17	43%	11	62%	6	80%	5	84%
356	E	E	0	100%	0	100%	5	83%	6	79%	4	87%	8	74%
Mean		A	0.0	100%	0.0	100%	18.0	40%	9.0	69%	7.3	76%	10.7	66%
+/- S.D.		T	0.0	0%	0.0	0%	13.5	45%	2.6	9%	4.2	14%	7.4	24%

SVR 155D Infestations were with 100 fleas

A = untreated control; B = bifenthrin, 0.025%; C = bifenthrin, 0.050%; D = bifenthrin, 0.075%; E = bifenthrin, 0.100%.

Results for ticks are summarized in Table 2. All four test material concentrations provided ≥94% control at 24 and 48 hours after treatment. All concentrations provided acceptable control at the succeeding time points, with the exception of the 0.025% concentration on days 7, 8, and 15.

Table 2.
Efficacy of Four Biphenthrin Shampoos against Fleas and Ticks on Dogs

Tick Counts

Days after Treatment		0	1		2		7		8		14		15	
Dog no	Group		No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
424	A		17		26		39		42		16		22	
381	A		26		32		29		26		18		17	
312	A		9		13		21		12		11		11	
Mean			17.3		23.7		29.7		26.7		15.0		16.7	
+/- S.D			8.5		9.7		9.0		15.0		3.6		5.5	
425	B	T	0	100%	0	100%	5	83%	5	81%	1	93%	3	82%
301	B	R	0	100%	0	100%	1	97%	3	89%	3	80%	3	82%
368	B	E	1	94%	3	87%	10	66%	4	85%	0	100%	3	82%
Mean		A	0.3	98%	1.0	96%	5.3	82%	4.0	85%	1.3	91%	3.0	82%
+/- S.D		T	0.6	3%	1.7	7%	4.5	15%	1.0	4%	1.5	10%	0.0	0%
425	C	T	0	100%	0	100%	1	97%	0	100%	0	100%	0	100%
301	C	R	0	100%	0	100%	0	100%	0	100%	2	87%	2	88%
368	C	E	0	100%	0	100%	0	100%	0	100%	1	93%	1	94%
Mean		A	0.0	100%	0.0	100%	0.3	99%	0.0	100%	1.0	93%	1.0	94%
+/- S.D		T	0.0	0%	0.0	0%	0.6	2%	0.0	0%	1.0	7%	1.0	6%
420	D	T	3	83%	0	100%	3	90%	0	100%	0	100%	0	100%
412	D	R	0	100%	0	100%	0	100%	0	100%	1	93%	2	88%
356	D	E	0	100%	0	100%	0	100%	0	100%	0	100%	1	94%
Mean		A	0.0	94%	0.0	100%	1.0	97%	0.0	100%	0.3	98%	1.0	94%
+/- S.D		T	0.0	10%	0.0	0%	1.7	6%	0.0	0%	0.6	4%	1.0	6%
420	E	T	0	100%	0	100%	4	87%	4	85%	4	73%	2	88%
412	E	R	0	100%	0	100%	0	100%	0	100%	0	100%	2	88%
356	E	E	0	100%	0	100%	0	100%	0	100%	0	100%	0	100%
Mean		A	0.0	100%	0.0	100%	1.3	96%	1.3	95%	1.3	91%	1.3	92%
+/- S.D		T	0.0	0%	0.0	0%	2.3	8%	2.3	9%	2.3	15%	1.2	7%

SVR 155D — Infestations were with 50 R.sanguineus ticks

A = untreated control; B = bifenthrin, 0.025%; C = bifenthrin, 0.050%; D = bifenthrin, 0.075%; E = bifenthrin, 0.100%.

Statistical significance for the results against fleas is given in Table 3. When compared to the untreated controls, all four test material concentrations provided significant control of fleas at all time points except day 7 (24 hours after re-infestation).

Table 3.

Efficacy of Four Biphenthrin Shampoos against Fleas and Ticks on Dogs
Significance of Apparent Differences in Flea Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	7	8	14	15
Comparing groups						
A vs B	< 0.001	< 0.001	< 0.05	< 0.05	< 0.05	< 0.02
A vs C	< 0.001	< 0.001	> 0.2	< 0.02	< 0.01	< 0.02
A vs D	< 0.001	< 0.001	> 0.05	< 0.05	< 0.01	< 0.02
A vs E	< 0.001	< 0.001	> 0.2	< 0.05	< 0.005	< 0.05
B vs C	= 1	= 1	> 0.4	> 0.8	> 0.4	> 0.4
B vs D	= 1	= 1	.0.05	> 0.8	> 0.2	> 0.8
B vs E	= 1	= 1	> 0.3	> 0.4	> 0.4	= 1
C vs D	= 1	= 1	> 0.9	> 0.4	< 0.05	> 0.5
C vs E	= 1	= 1	> 0.9	> 0.3	> 0.9	> 0.6
D vs E	= 1	= 1	> 0.9	> 0.7	< 0.02	> 0.9

SVR 155D

A = untreated control; B = bifenthrin, 0.025%; C = bifenthrin, 0.050%; D = bifenthrin, 0.075%; E = bifenthrin, 0.100%.

Statistical significance for the results against ticks is given in Table 4. Compared to the untreated controls, all four test material concentrations provided significant control of ticks, with the exception of the 0.025% concentration on day 8 and the 0.075% and 0.100% concentrations on day 15.

Table 4.

Efficacy of Four Biphenthrin Shampoos against Fleas and Ticks on Dogs
Significance of Apparent Differences in Tick Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	7	8	14	15
Comparing groups						
A vs B	< 0.05	< 0.02	< 0.02	> 0.05	< 0.005	< 0.02
A vs C	< 0.05	< 0.02	< 0.005	< 0.05	< 0.005	< 0.01
A vs D	< 0.05	< 0.02	< 0.01	< 0.05	< 0.005	> 0.01
A vs E	< 0.05	< 0.02	< 0.01	< 0.05	< 0.01	> 0.01
B vs C	> 0.3	> 0.3	> 0.1	< 0.005	> 0.7	< 0.05
B vs D	> 0.5	= 1	> 0.1	< 0.005	> 0.3	< 0.05
B vs E	> 0.3	= 1	> 0.2	> 0.1	=1	> 0.05
C vs D	> 0.3	= 1	> 0.5	= 1	> 0.3	= 1
C vs E	= 1	= 1	> 0.5	> 0.3	> 0.8	> 0.7
D vs E	> 0.3	= 1	> 0.8	> 0.3	> 0.8	> 0.7

SVR 155D

A = untreated control; B = bifenthrin, 0.025%; C = bifenthrin, 0.050%; D = bifenthrin, 0.075%; E = bifenthrin, 0.100%.

Study Author's Conclusions

The study author concluded that all four concentrations of the test material were equally and completely effective against existing fleas, but not effective against new fleas applied at 6 and 13 days after treatment. All four concentrations were close to 100% effective against existing ticks, and the three highest concentrations were effective against new ticks applied on days 6 and 12.

Reviewers Conclusions

The reviewer agrees with the study author's conclusions. The 0.050% bifenthrin concentration used in the test is equivalent to the concentration given on the Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs, and results for that concentration support the label claims listed below.

Reviewer Recommendations

This study supports the following label claims for Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs:

Kills …Ticks for [15 days] [2 weeks]
Kills for [15 days] [2 weeks]…Ticks
Active against fleas
Active against ticks
Kills [fleas] [and] [ticks]

It does not support the following label claims:

Kills Fleas…for [15 days] [2 weeks]
Kills for [15 days] [2 weeks] Fleas…

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 481222-18

OCSPP 810.3300

Product Name: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs
EPA File Symbol: 2517-RGO
Decision number: 435344
DP number: 381023

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-33

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 27 2011

Secondary Reviewers:
Robert Ross, M.S.

Signature: Robert N. Ross
Date: OCT 27 2011

Robert Ross, M.S., Program Manager

Signature: Robert N. Ross
Date: OCT 27 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: OCT 27 2011

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

Summitec Corporation for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE (OCSPP 810.3300)
MRID:	481222-18. Efficacy of a Biphenthrin Shampoo Against Fleas and Ticks on Dogs. Sharp, M. 2009.
DP BARCODE:	381023
DECISION NO:	435344
SUBMISSION NO:	876525
SPONSOR:	Sergeant's Pet Care Products, Inc., 2625 South 158th Plaza, Suite 100, Omaha, NE 68130-1703
TESTING FACILITY:	Sharp Veterinary Researeh, PO Box 353, 2500 Tolar St., Vernon, TX 76385
STUDY DIRECTOR:	Marvin Sharp, D.V.M.
SUBMITTER:	Kelly R. Hoskins, Manager of Technical Affairs, Sergeant's Pet Care Products, Inc.
STUDY COMPLETED:	06/04/2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was provided. The study does not meet the requirements of 40 CFR Part 160, since the statistical methods used the statistical package in Microsoft Excel version 97 SR-1, and the user cannot validate Microsoft's proprietary code in this software.
TEST MATERIAL:	PRODUCT NAME: Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs EPA FILE SYMBOL: 2517-RGO ACTIVE INGREDIENT NAME: Bifenthrin CHEMICAL NAME: Not provided A.I. %: 0.05 PC CODE: 128825 CAS NO.: 82657-04-3

FORMULATION TYPE: Liquid shampoo
PRODUCT APPLICATION RATE(S): Not provided
ACTIVE INGREDIENT APPLICATION RATE(S): Not provided

PROPOSED LABEL MARKETING CLAIMS:

Active against fleas
Active against ticks
Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks]

STUDY REVIEW

Purpose: The study was conducted to determine the efficacy of 0.025% bifenthrin against fleas and ticks on dogs.

MATERIALS AND METHODS

Test Location: Vernon, TX

Test Material(s): The test material was a shampoo containing bifenthin (0.025% w/w). The mean group dose rate delivered to the dogs was 1.25 mg bifenthrin/kg. The Sergeant's® Bifenthrin Shampoo [with Oatmeal] for Dogs product label does not specify an application rate.

Test Species Name, Life Stage, Sex and Age: Flea (*Ctenocephalides felis*), sex not reported, adults; tick (*Dermacentor variabilis*), sex not reported, adults; tick (*Rhipicephalus sanguineus*), sex not reported, adults

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: According to the study protocol, the dogs were to be acclimated to the test facility for approximately 14 days, during which they were pre-tested for ability to hold a viable population of adult fleas and ticks (*R. sanguineus*). The dogs were washed with a non-insecticidal shampoo at least one day prior to the pretest infestation with the test organisms. After washing, the dogs were to be thoroughly combed to remove any residual fleas and ticks. The animals were housed in 3 x 10 ft runs in sheltered housing units, and provided PMI nutrition 27% high protein dog food and fresh water *ad libitum*.

The dogs were allocated to groups (6 dogs/group) by body weight, and on the day before treatment were infested with unfed fleas and ticks. Two test material groups were included in the test. Each test material group was infested with 100 unfed fleas. Additionally, one of those groups was

infested with 50 unfed *R. sanguineus* ticks, and the other with 50 *D. variabilis* ticks. Two similarly infested groups served as untreated controls. All groups were re-infested 7 days after treatment.

At test start, the test material group dogs were treated with the test material shampoo. According to the study protocol, each dog's coat was wetted with water and the shampoo was applied at a rate of approximately 5 g/kg. The shampoo was massaged into the coat until a substantial lather covered the entire body surface, including limbs, tail, and head. The lather was allowed to sit for 5 minutes, then removed by rinsing with water. The dogs were then blown dry. The control group was not treated.

Flea and tick counts were made on days 1 and 2 after treatment and on days 8 and 9 after treatment (1 and 2 days after re-infestation). The day 1 and day 8 counts were timed body/hand counts without removing the parasites. The day 2 and day 9 counts were comb counts that removed all fleas and ticks.

List the treatments including untreated control: The test material group received 5 g/kg of shampoo containing 0.025% bifenthrin, for a dose of 1.25 mg bifenthrin/kg; the control group was not treated.

Number of replicates per treatment: 2

Number of individuals per replicate: Fleas: 100; ticks (*R. sanguineus*): 50; ticks (*D. variabilis*): 50

Length of exposure to treatment: Up to 2 days

Experimental conditions: Not reported.

Data or endpoints that were to be collected/recorded: Number of surviving fleas and ticks.

Statistical analyses: Efficacy was calculated as:

$$\frac{\text{Mean no. of live fleas/ticks on untreated dogs} - \text{mean no. of live fleas/ticks on treated dogs}}{\text{Mean no. of live fleas/ticks on untreated dogs}} \times 100$$

Individual efficacy values were calculated as percent reduction from the mean control group count. Group efficacy (mean ± std deviation) was calculated from the aggregate individual efficacy values. Significant differences in flea and tick counts between the treated and control dogs were determined by Student's "t" test, using the statistical program in Microsoft Excel version 97 SR-1. The significance level was 5%.

RESULTS

Were the raw data included? No.

Protocol amendments and deviations: None reported.

Describe and report experimental results in the untreated controls and treatments: Results for fleas are summarized in Table 1. Compared to the untreated controls, mean efficacy of the test material was 95% at 24 hours after treatment, and 96% at 48 hours after treatment. The test material was less effective against the second infestation of fleas, with a mean efficacy of 50% at 24 hours after re-infestation (8 days after treatment) and 62% at 48 hours after re-infestation (9 days after treatment).

Table 1.

Efficacy of a Biphenthrin Shampoo against Fleas and Ticks on Dogs

Flea Counts

Days after Treatment		0	1		2		8		9	
Dog no.	Group		No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
468	C 1		23		20		33		30	
350	C 1		25		23		46		43	
357	C 1		32		16		63		48	
463	C 1		36		29		35		37	
461	C 1		18		20		36		34	
449	C 1		53		51		30		32	
Mean			31.2		26.5		40.5		37.3	
+/- S.D.			12.5		12.8		12.3		6.9	
464	C 2		33		27		32		30	
392	C 2		19		14		31		35	
380	C 2		31		16		36		33	
312	C 2		28		20		24		32	
458	C 2		18		18		16		18	
427	C 2		36		32		38		36	
Mean			27.5		21.2		29.5		30.7	
+/- S.D.			7.4		6.9		8.2		6.6	
Mean	C 1 & C 2		29.3		23.8		35.0		34.0	
466	B	T	1	97%	0	100%	21	48%	18	52%
436	B	R	0	100%	0	100%	27	33%	14	63%
422	B	E	0	100%	1	96%	21	48%	13	65%
224	B	A	0	100%	0	100%	22	46%	11	71%
381	B	T	4	87%	0	100%	10	75%	11	71%
378	B		0	100%	0	100%	5	88%	3	92%
Mean			0.8	97%	0.2	99%	17.7	50%	11.7	64%
+/- S.D.			1.6	6%	0.4	2%	8.3	15%	5.0	8%
328	A 1	T	0	100%	0	100%	21	48%	15	60%
408	A 1	R	4	87%	7	74%	21	48%	18	52%
222	A 1	E	0	100%	1	96%	37	9%	23	38%
361	A 1	A	0	100%	0	100%	25	38%	15	60%
431	A 1	T	1	97%	1	96%	35	14%	26	30%
229	A 1		0	100%	0	100%	16	60%	12	68%
Mean			0.8	97%	1.5	93%	25.8	31%	18.2	48%
+/- S.D.			1.6	6%	2.7	11%	8.4	19%	5.3	13%
457	A 2	T	0	100%	0	100%	28	31%	16	57%
230	A 2	R	0	100%	0	100%	6	85%	6	84%
226	A 2	E	8	74%	1	96%	12	70%	9	76%
228	A 2	A	2	94%	0	100%	10	75%	9	76%
465	A 2	T	0	100%	0	100%	6	85%	4	89%
471	A 2		0	100%	1	96%	30	26%	10	73%
Mean			1.7	94%	0.3	99%	15.3	69%	9.0	76%
+/- S.D.			3.2	11%	0.5	2%	10.9	22%	4.1	12%
Mean	A 1 & A 2		1.3	95%	0.9	96%	20.6	50%	13.6	62%

A1 & A2 are treated groups, C1 & C2 are control groups. B is a positive control.

Results for ticks are summarized in Table 2. Compared to the untreated controls, mean efficacy of the test material against *D. variabilis* was 54% at 24 hours after treatment, and 67% at 48 hours after treatment. The test material was less effective against the second infestation of *D. variabilis*, with a mean efficacy of 23% at 24 hours after re-infestation (8 days after treatment) and 28% at 48 hours after re-infestation (9 days after treatment). Against *R. sanguineus*, mean efficacy of the test material was 82% at 24 hours after treatment and 85% at 48 hours after treatment. The test material was less effective against the second infestation of *R. sanguineus*, with a mean efficacy of 32% at 24 hours after re-infestation (8 days after treatment) and 50% at 48 hours after infestation (9 days after treatment).

Table 2.

Efficacy of a Biphenthrin Shampoo against Fleas and Ticks on Dogs

Tick Counts

Days after Treatment		Tick		0	1		2		8		9	
Dog no.	Group	sp			No.	Eff %	No.	Eff %	No.	Eff %	No.	Eff %
468	C 1	*D.v.*			32		23		33		32	
350	C 1	*D.v.*			48		46		37		34	
357	C 1	*D.v.*			49		45		47		49	
463	C 1	*D.v.*			47		43		38		41	
461	C 1	*D.v.*			39		42		37		42	
449	C 1	*D.v.*			46		49		28		34	
Mean					43.5		41.3		36.7		38.7	
+/- S.D.					6.7		9.3		6.3		6.5	
464	C 2	*R.s.*			46		41		41		46	
392	C 2	*R.s.*			12		10		12		15	
380	C 2	*R.s.*			31		24		20		28	
312	C 2	*R.s.*			32		26		21		18	
458	C 2	*R.s.*			20		21		17		19	
427	C 2	*R.s.*			37		34		27		20	
Mean					29.7		26.0		23.0		24.3	
+/- S.D.					12.1		10.7		10.1		11.5	
466	B	*R.s.*	T		4	87%	0	100%	14	39%	9	63%
436	B	*R.s.*	R		3	90%	0	100%	18	22%	7	71%
422	B	*R.s.*	E		6	80%	0	100%	8	65%	6	75%
224	B	*R.s.*	A		2	93%	0	100%	7	70%	6	75%
381	B	*R.s.*	T		2	93%	0	100%	37	-61%	15	38%
378	B	*R.s.*			1	97%	2	92%	8	65%	9	63%
Mean					3.0	89%	0.3	100%	15.3	27%	8.7	65%
+/- S.D.					1.8	6%	0.8	0%	11.4	53%	3.4	16%
328	A 1	*D.v.*	T		18	59%	10	76%	26	29%	28	28%
408	A 1	*D.v.*	R		28	36%	9	78%	23	37%	25	35%
222	A 1	*D.v.*	E		24	45%	24	42%	34	7%	31	20%
361	A 1	*D.v.*	A		18	59%	16	61%	35	5%	34	12%
431	A 1	*D.v.*	T		11	75%	10	76%	24	35%	22	43%
229	A 1	*D.v.*			18	59%	14	66%	40	-9%	44	-14%
Mean					19.5	54%	13.8	67%	30.3	23%	30.7	28%
+/- S.D.					5.9	15%	5.7	15%	6.9	15%	7.8	12%
457	A 2	*R.s.*	T		4	87%	4	85%	15	35%	12	51%
230	A 2	*R.s.*	R		4	87%	4	85%	9	61%	7	71%
226	A 2	*R.s.*	E		7	76%	7	73%	38	-65%	31	-27%
228	A 2	*R.s.*	A		2	93%	2	92%	11	52%	8	67%
465	A 2	*R.s.*	T		9	70%	3	88%	5	78%	3	88%
471	A 2	*R.s.*			9	70%	7	73%	42	-83%	37	-52%
Mean					5.8	82%	4.5	85%	20.0	32%	16.3	50%
+/- S.D					2.9	9%	2.1	7%	15.9	57%	14.1	45%

A1 & A2 are treated groups, C1 & C2 are control groups. B is a positive control. R.s. = *Rhipicephalus sanguineus,* D.v. = *Dermacentor variabilis*

Statistical significance for the results against fleas is given in Table 3. When compared to the untreated controls, the test material provided statistically significant control of fleas at each time point.

Table 3.

Efficacy of a Biphenthrin Shampoo against Fleas and Ticks on Dogs
Significance of Apparent Differences in Flea Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	8	9
Comparing groups				
A vs C	**< 0.0001**	**< 0.0001**	**< 0.05**	**< 0.0001**
B vs C	**< 0.0001**	**< 0.0001**	**< 0.005**	**< 0.0001**
A vs B	> 0.7	> 0.3	> 0.5	> 0.5

SVR 162D

Groups C! & C2 flea counts are combined as "C"
Groups A! & A2 flea counts are combined as "A"
Significantly lower flea counts

B is a positive control

Statistical significance for the results against ticks is given in Table 4. Compared to the untreated controls, the test material provided statistically significant control of both *R. sanguineus* and *D. variabilis* at 24 and 48 hours after treatment, but not afterwards.

Table 4.

Efficacy of a Biphenthrin Shampoo against Fleas and Ticks on Dogs

Significance of Apparent Differences in Tick Counts

"P" values by Student's "t" test assuming equal variances

Day of Study	1	2	8	9
Comparing groups				
A 1 vs C 1	< 0.0005	< 0.0001	> 0.1	> 0.05
A 2 vs C 2	< 0.001	< 0.001	> 0.7	. 0.3
B vs C 2	< 0.0005	< 0.0002	> 0.2	< 0.01
A 1 vs A 2	< 0.001	< 0.005	> 0.1	> 0.5
A 2 vs B	> 0.05	< 0.005	> 0.5	> 0.2

SVR 162D

Significantly lower flea counts

tick

Study Author's Conclusions

The study author concluded that group efficacy against fleas exceeded 90% at 24 and 48 hours after treatment, but was substantially reduced after re-infestation with new fleas at day 7. Efficacy against *R. sanguineus* and *D. variabilis* did not attain a group mean of 90%.

Reviewers Conclusions

The reviewer agrees with the study author's conclusions.

Reviewer Recommendations

This study supports the following label claims:

Active against fleas
Active against ticks

Kills…ticks…
Kills…fleas…
Kills adult fleas…
Kills [fleas] [and] [ticks]